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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,905	09/29/1999	KENNETH WALSH	S1237/7011/E	4597

7590

07/15/2002

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/15/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/408,905

Applicant(s)

WALSH, KENNETH

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The request filed on 11-26-01 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/408905 is acceptable and a RCE has been established.

Claims 1-38 are pending.

Claims 6-38 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-5 are pending and are currently under consideration.

This Action is in response to Applicant's After-Final Response (received June 6, 2002). Applicant's indicate that in view of the June 6, 2002, telephone conference, it was there understanding that the Examiner would cancel the Office Action of January 15, 2002 and issue a NEW Final Office Action which takes into account the previously submitted, executed Declaration of K. Walsh. A review of the history of this case indicates that a Final Rejection was mailed on January 15, 2002 (Paper No. 21). That action was based on an RCE and unsigned declaration (received 11-26-01, Paper Nos: 18-20). Applicant's signed Declaration was entered into the case on January 9, 2002 (Paper No. 22). Thus, since the signed Declaration was not previously considered, the previous Office Action (Paper No. 21) is hereby vacated.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

## Rejections Maintained

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cuevas et al. (Eur.J.Med.Res, Vol. 2, pages 465-468, November, 1997) in view of Datta et al. (Cell, Vol. 91, pages 231-241, October, 1997) for the reasons of record. (see Paper No. 13, pages 4-5 and Paper No. 16).

Applicant's Declaration (Paper No. 22) and after-final response (Paper No. 23) are not found persuasive for the following reasons:

1. Contrary to the statement in the Declaration on page 3, Item 9, Exhibit A establishes a date in November of 1997 which is after the publication date of the prior art Datta *et al.* (Declaration, page 2, No. 5).
2. Applicants argue (Paper No. 23, page 3) that the Walsh declaration of Exhibit B includes evidence from April 1996 that Akt promotes endothelial cell viability in response to VEGF. Applicants further argue that the Walsh Declaration Exhibit B includes the results of experiments which correspond to those described in Example 2 of the application as filed (Figures 3A-B). This argument has been considered but is not found persuasive. Although the experiment in Exhibit B (page 6) was preformed prior to the Datta *et al.* reference, such results do not establish due diligence in reducing the invention to practice for the following reasons:

- a. The Declarant does not fully describe the experiments preformed in Exhibit B, only that Exhibit B establishes due diligence (Declaration, page 3, Item 10).  
Furthermore, the results, as presented in Exhibit B are incomplete as the Y-axis is not labeled. Hence, applicant's interpretation, (that the results show that Akt expression can enhance the sensitivity of endothelial cells to VEGF survival signals) appears inconsistent because the data presented in Exhibit B do not adequately reflect the arguments of counsel. Furthermore, the arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964).
- b. The experiment preformed in Exhibit B do not establish due diligence in reducing the invention to practice. Assuming arguendo, that Exhibit B does in fact show that Akt expression can enhance the sensitivity of endothelial cells to VEGF survival signals, the claimed invention is broadly drawn to a method for treating myocardial infarction comprising administering to a subject in need of such treatment an Akt molecule in an amount effective to inhibit cardiac tissue necrosis in the subject. The sole experiment of Exhibit B does not extrapolate to nor approach due diligence in reducing to practice a method of treating a myocardial infarction because there is insufficient guidance and objective evidence that such data would be indicative or predictive that a myocardial infarction would be treated in an individual by administering an Akt molecule. Those of skill in the

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art recognize that in vitro assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in- vitro assay does not permit a single extrapolation of in vitro assays to human diagnostic or treatment efficacy with any reasonable degree of predictability.

Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

**Claim Objections:**

Claim 5 remains objected to for the reasons of record in Paper No. 13, page 5.

***Conclusion***

This is an RCE of applicant's earlier Application No. 09/408905. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

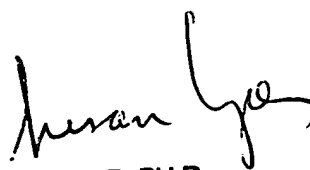
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
July 1, 2002

  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER